



DEFENSE LOGISTICS AGENCY

AMERICA'S COMBAT LOGISTICS SUPPORT AGENCY



ISO 9001

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Purpose of Higher-Level Quality Requirements

- **Higher-level quality requirements**

- Control work operations, in-process controls, and inspections
- Bring attention to organization, planning, work instructions, documentation control, and advanced methodology
- Help ensure quality requirements are met on complex and critical items



QMS Documentation

- Contracts with higher-level quality requirements require supplier to establish and maintain a documented QMS
- QMS documentation may consist of:
 - Supplier quality manual/contract-specific quality plan
 - Support process procedures, may be part of quality manual/plan
 - Manufacturing process procedures, to include inspection and testing

DCMA does NOT approve/accept supplier's QMS, but reserves the right to disapprove procedures based on the results of GCQA surveillance.



Contractor (Supplier) Responsibilities

- According to **FAR 46.105**, supplier must carry out contractual QA obligations by:
 - Controlling quality of product/ service
 - Ensuring their vendor's have acceptable quality control system
 - Maintaining evidence that products/services conform to contract quality requirements
 - Tendering to the Government *ONLY* products/services that conform to contract requirements



HIGHER LEVEL QUALITY SYSTEMS

- In 1995 MIL-I-45208 and MIL-Q-9858 were cancelled with guidance issued to use ISO 9001, ISO 9002, ISO 9003, ANSI/ASQC Q9001, Q9002, Q9003 or a comparable non-Government quality system.
- In 1996 a second notice was published cancelling both specifications without replacement.
- However, these specifications are still referenced by contractors frequently today.



MIL-Q-9858

- MIL-Q-9858 was required whenever the contract had technical requirements such as:
 - control of work operations
 - in-process control
 - inspection
 - organization
 - work instructions
 - documentation control
 - advanced metrology
- This specification was intended for use in contracts involving complex types of military hardware and systems.
- ISO 9001 replaced MIL-Q-9858 when it was cancelled.



MIL-I-45208

- Established requirements for contractors' inspection systems and tests necessary to substantiate product conformance.
- The specification was used when technical requirements cited "Process controls" as well as "Final End Item Inspection." For example:
 - measuring and testing equipment
 - drawings and changes
 - documentation and records
 - Non-conforming material
- It required companies to document their inspection system to assure continuity.
- ISO 9002 was the original replacement for MIL-I-45208 when it was cancelled. ISO 9002 was cancelled/replaced in 1994 by ISO 9001.



International Standards Organization - ISO

- The increase in international trade stimulated the development of internationally recognized quality management standards.
- Sets out the criteria for a quality management system, but does not dictate how it should be met in any particular organization.
- It promotes the adoption of a process-approach and continual improvement.
- Specifies requirements for a quality management system that can be used by any organization, or for certification, or for contractual purposes
- Generic Management System Standards



International Standards Organization - ISO

- Requires the organization **ITSELF** to audit its ISO 9001-2008 based quality system to verify that it is managing its processes effectively. (to check that it is fully in control of its activities)
- The organization **may** invite its clients to audit the quality system in order to give them confidence.
- Organization **may** engage the services of an independent quality system certification body to obtain a ISO 9001-2008 certificate of conformity. (Third Party Certification)



Defense Contract Management Agency-DCMA

- DCMA assures compliance with higher level quality requirements when they do their QMS audits/reviews.
- DCMA QA personnel prepare the audit report. The report is retained by DCMA in accordance with the DCMA Records Management instruction.
- The System Audit is performed in accordance with the GCQA Surveillance plan.
- If the audit results require the supplier to take corrective action, the appropriate level Corrective Action Request (CAR) will be issued in accordance with the Corrective Action Process instruction with responsibility for follow up and closure assigned to the applicable QA personnel.



Defense Contract Management Agency-DCMA

- DCMA Instruction 322 - Quality System Audit. The entire QMS shall be reviewed every three years, as stated in the GCQA Surveillance Planning Instruction, unless the results of the risk assessment or customer direction warrants more frequent audits. DCMA System Audit is considered a second party audit of the QMS and as such is more thorough than what will be accomplished during a third party audit.
- DCMA Instruction 303 - Critical Safety Items QA "Ensures DCMA surveillance is intensively focused on CSIs to mitigate risk of failure of those items with characteristics, which if nonconforming, would likely cause serious injury or death to the user or catastrophic failure of a major platform and to assure conformity of those items prior to acceptance."



FAR Clause 52.246-11

52.246-11 -- Higher-Level Contract Quality Requirement.

As prescribed in [46.311](#), insert the following clause:

Higher-Level Contract Quality Requirement (Dec 2014)

(a) The Contractor shall comply with the higher-level quality standard selected below.

	Title	Number	Date	Tailoring

[Contracting Officer insert the title, number (if any), date, and tailoring (if any) of the higher-level quality standards.]



FAR Clause 52.246-11 con't

(b) The Contractor shall include applicable requirements of the higher-level quality standard(s) listed in paragraph (a) of this clause and the requirement to flow down such standards, as applicable, to lower-tier subcontracts, in –

(1) Any subcontract for critical and complex items (see 46.203(b) and (c)), or

(2) When technical requirements of a subcontract require—

(i) Control of such things as design, work operations, in-process control, testing and inspection; or

(ii) Attention to such factors as organization, planning, work instruction, documentation control, and advance metrology.

(End of Clause)



Higher Level Contract Quality Requirements

- The Higher-Level Contract Quality Requirements clause requires the contractor to implement one or more of the documented quality systems that meets the applicable standard(s) cited in the contract:
 - International Standardization Organization (ISO) standard(s)
 - Other recognized applicable industry standard(s) and/or
 - Specified Government requirement
- For evaluation purposes, any higher-level contract quality system proposed by the contractor needs to provide for the Government's ability to audit/validate its capabilities to ensure the safety and satisfaction of our customers.



Higher Level Contract Quality Requirements (non-manufacturer)

As prescribed in 46.311, insert the following clause: Higher-Level Contract Quality Requirement (Non-Manufacturers) (NOV 2011) – DLAD 52.246-9043

If a higher-level contract quality requirement applies to this contract and the Contractor is not the actual manufacturer of the item(s) to be furnished, the contractor represents that it shall:

- (a) Furnish items under this contract that were produced at a manufacturing facility conforming to the higher-level contract quality requirement specified in FAR 52.246-11; or
- (b) Maintain and provide objective evidence that items furnished under this contract were produced at a manufacturing facility conforming to the specified higher-level contract quality requirement and that the material meets contract requirements. At a minimum, evidence shall be sufficient to establish the identity of the product and its manufacturing source; and
- (c) Maintain documentation of its quality assurance program; receiving/verification process; records management system; procurement system; inventory control system; testing results; and any other records identified in this contract.



Higher Level Contract Quality Requirements

- Effective November 01, 2013, MIL-I-45208 is no longer considered an acceptable quality management standard when higher level quality is required on the material (FAR Clause 52.246-11).
- Notice was published in DLA Internet Bid Board System (DIBBS) and Supplier Information Resource Center (SIRC.)
- Many manufacturers will find their current quality management system conforms to either the Tailored ISO 9001:2008 or SAE AS9003 with only minor adjustments necessary to their own quality plan.
- Examples of higher-level quality standards include overarching quality management system standards such as ISO 9001, ASQ/ANSI E4; ASME NQA-1, SAE AS9100, SAE AS9003, and ISO/TS 16949, and product or process specific quality standards such as SAE AS5553.



STO ZD059-Tailored ISO 9001

52.246-11 Higher Level Contract Quality Requirement (Manufacturers)

- FAR CLAUSE 52.246-11 APPLIES. A QUALITY MANAGEMENT PROGRAM MEETING THE REQUIREMENTS OF ISO 9001:2008; A PROGRAM COMPARABLE TO ISO 9001:2008 (EXAMPLE SAE AS 9100), THE FOLLOWING TAILORED VERSION OF ISO 9001:2008; OR A PROGRAM COMPARABLE TO THE TAILORED VERSION OF ISO 9001:2008 (EXAMPLE SAE AS 9003) IS REQUIRED. MIL-I-45208 AND MIL-Q-9858 ARE OBSOLETE AND NO LONGER CONSIDERED SUITABLE WHEN HIGHER LEVEL QUALITY IS REQUIRED. IN THE TAILORED VERSION OF THE ISO 9001:2008, ANY REFERENCES WHICH CITE THE ENTIRE INTERNATIONAL STANDARD ARE INTERPRETED AS EXCLUSIONS TO THIS DOCUMENT.

~~4.1 General requirements, [excluding reference to 1.2 and excluding NOTE 3 c)]~~
DLA TAILORED HIGHER LEVEL QUALITY CLAUSE FROM ISO 9001:2008

4.2.1 General, [excluding subparagraph a)]

4.2.2 Quality manual, [excluding subparagraph a)]

4.2.3 Control of documents

4.2.4 Control of records

5.1 Management commitment

5.3 Quality policy

6.2.2 Competence, training and awareness

6.4 Work environment



STO ZD059-Tailored ISO 9001

- 7.1 Planning of product realization, [excluding NOTE 2]
- 7.2.1 Determination of requirements related to the product
- 7.2.2 Review of requirements related to the product
- 7.2.3 Customer communication
- 7.3.7 Control of design and development changes
- 7.4.1 Purchasing process
- 7.4.3 Verification of purchased product
- 7.5.1 Control of production and service provision
- 7.5.3 Identification and traceability
- 7.5.4 Customer property
- 7.5.5 Preservation of product
- 7.6 Control of monitoring and measuring equipment
- 8.1 General, [excluding subparagraph b) and subparagraph c)]
- 8.2.2 Internal audit
- 8.2.4 Monitoring and measurement of product
- 8.3 Control of nonconforming product
- 8.5.2 Corrective action
- 8.5.3 Preventive action



Comparison of Tailored ISO 9001, AS9003, MIL-I-

	Tailored ISO 9001	AS9003	MIL-I-45208
General Requirements [excluding reference to 1.2 and note 3.c)]	4.1	4.1	3.1
Documentation reqmts [excluding subpara a)]	4.2.1	4.2	3.2
Quality Manual [excluding subpara a)]	4.2.2	4.2.1	3.4
Control of Documents	4.2.3	4.2.2	3.2.1
Control of Records	4.2.4	4.2.3	3.2.2
Management Commitment	5.1	5.1	not addressed
Quality Policy	5.3	not addressed	not addressed
Competence, training, awarness	6.2.2	6.1	not addressed
Work Environment	6.4	6.2	3.5
Planning of prod. Realization	7.1	7.1	3.11
Configuration Management	not addressed	7.1.1	not addressed
Determination of reqmts related to product	7.2.1	7.2	3.11.2
Review of reqmts related to product	7.2.2	7.2	not addressed
Customer Communication	7.2.3	7.2	not addressed
Control of design & dev changes	7.3.7	not addressed	not addressed
Purchasing Process	7.4.1	7.4.1	not addressed
Purchasing Information	not req'd	7.4.2	not addressed
Verification of purchased product	7.4.3	7.4.3	3.11.2
Control of production & service	7.5.1	7.5.1	3.4
Production Process Verification	not req'd	7.5.1.1	3.4
Control of Production Process Changes	not req'd	7.5.1.2	3.4
Identification & traceability	7.5.3	7.5.2	Pkg reqmts of contract
Customer Property	7.5.4	not addressed	3.6
Preservation of product	7.5.5	7.5.3	Pkg reqmts of contract



Comparison of ISO 9001-2008 and ISO 9001-2015

ISO 9001-2008	ISO 9001-2015
4-Quality Management System (just a heading)	4.4 Quality management system and its processes (just a heading)
4.1 General Requirements	4.4.1
4.2 Documentation requirements	4.4.2, 7.5.1 Documentation information General; 7.5.2 Creating and updating
4.2.2 Quality Manual	Table A.1 indicates 'quality manual' is covered under 'documented information'
4.2.3 Control of documents	7.5.3 Control of documented information
4.2.4 Control of records	7.5.3 Control of documented information
5 Management responsibility (just a heading)	5 Leadership (just a heading)
5.1 Management commitment	5.1 Leadership and commitment
5.2 Customer focus	5.1.2 Customer focus
5.3 Quality policy	5.2 Policy; 5.2.1 Establishing the quality policy; 5.2.2 Communicating the quality policy



Comparison of ISO 9001-2008 and ISO 9001-2015

ISO 9001-2008	ISO 9001-2015
5.4 Planning (just a heading)	6 Planning (just a heading)
	6.1 Actions to address risks and opportunities
5.4.1 Quality objectives	6.2.1 Quality objectives and planning to achieve them
5.4.2 Quality management system planning	6.2 Quality objectives and planning to achieve them; 6.3 Planning of changes
5.5 Responsibility, authority and communication (just a heading)	
5.5.1 Responsibility and authority	5.3 Organizational roles, responsibilities and authorities
5.5.2 Management representative	5.3 Organizational roles, responsibilities and authorities
5.6 Management review (just a heading)	9.3 Management review (just a heading)
5.6.1 General	9.3.1 General
5.6.2 Review input	9.3.2 Management review inputs



Comparison of ISO 9001-2008 and ISO 9001-2015

ISO 9001-2008	ISO 9001-2015
5.6.3 Review output	9.3.3 Management review outputs
6 Resource management (just a heading)	7.1 Resources (just a heading)
6.1 Provision of resources	7.1.1 General
6.2 Human resources (just a heading)	
6.2.1 General	7.1.2 People
6.2.2 Competence, training and awareness	7.2 Competence, 7.3 Awareness, 7.4 Communication
6.3 Infrastructure	7.1.3 Infrastructure
6.4 Work environment	7.1.4 Environment for the operation of processes
no comparable section	7.1.6 Organizational knowledge
7 Product realization (just a heading)	



Comparison of ISO 9001-2008 and ISO 9001-2015

ISO 9001-2008	ISO 9001-2015
7.1 Planning of product realization	8.1 Operational planning and control
7.2 Customer-related processes (just a heading)	
7.2.1 Determination of requirements related to the product	8.2.2 Determining the requirements for products and services
7.2.2 Review of requirements related to the product	8.2.3 Review of the requirements for products and services; 8.2.4 Changes to requirements for products and services
7.2.3 Customer communication	8.2.1 Customer communication
7.3 Design and development (just a heading)	8.3 Design and Development of products and services (just a heading)
7.3.1 Design and development planning	8.3.1 General; 8.3.2 Design and development planning
7.3.2 Design and development inputs	8.3.3 Design and development inputs
7.3.3 Design and development outputs	8.3.5 Design and development outputs
7.3.4 Design and development review	8.3.4 Design and development controls



Comparison of ISO 9001-2008 and ISO 9001-2015

ISO 9001-2008	ISO 9001-2015
7.3.5 Design and development verification	8.3.4 Design and development controls
7.3.6 Design and development validation	8.3.4 Design and development controls
7.3.7 Control of design and development changes	8.3.6 Design and development changes
7.4 Purchasing (just a heading)	8.4 Control of externally provided processes, products and services (just a heading)
7.4.1 Purchasing process	8.4.1 General
7.4.2 Purchasing information	8.4.2 Type and extent of control
7.4.3 Verification of purchased product	8.4.3 Information for external providers
7.5 Production and service provision (just a heading)	8.5 Production and service provision (just a heading)
7.5.1 Control of production and service provision	8.5.1 Control of production and service provision
7.5.2 Validation of processes for production and service provision	8.5.1(f) validation



Comparison of ISO 9001-2008 and ISO 9001-2015

ISO 9001-2008	ISO 9001-2015
7.5.3 Identification and traceability	8.5.2 Identification and traceability
7.5.4 Customer property	8.5.3 Property belonging to customers or external providers
7.5.5 Preservation of product	8.5.4 Preservation
7.2.1(a) and Note; 7.5.1(f)	8.5.5 Post-delivery activities
no comparable section	8.6 Control of changes
7.6 Control of monitoring and measuring equipment	7.1.5 Monitoring and measuring resources 7.1.5.1 General, 7.1.5.2 Measurement traceability
8 Measurement, analysis and improvement (just a heading)	9 Performance evaluation (heading) 9.1 Monitoring, measurement, analysis and evaluation (just a heading)
8.1 General	9.1.1 General
8.2 Monitoring and measurement (just a heading)	
8.2.1 Customer satisfaction	9.1.2 Customer satisfaction



Comparison of ISO 9001-2008 and ISO 9001-2015

ISO 9001-2008	ISO 9001-2015
8.2.2 Internal audit	9.2 Internal Audit
8.2.3 Monitoring and measurement of processes	7.1.5.1 Monitoring and measuring resources (General)
8.2.4 Monitoring and measurement of product	8.6 Release of products and services; 9.1.1 General (Monitoring, measurement, analysis and evaluation)
8.3 Control of nonconforming product	10.1 Improvement (General)
8.4 Analysis of data	9.1.3 Analysis and evaluation
8.5 Improvement (just a heading)	
8.5.1 Continual improvement	10.3 Continual improvement
8.5.2 Corrective action	10.2 Nonconformity and corrective action
8.5.3 Preventive action	8.5.1(g) Control of production and service provision (prevent human error), 8.7 (Control of nonconforming outputs), 10.1(b) Improvement - General (b) correcting, preventing or reducing undesired effects



REFERENCES

- **DFARS 246.202-4** HIGHER LEVEL CONTRACT QUALITY REQUIREMENTS
- **DLAD 46.4** GOVERNMENT CONTRACT QUALITY ASSURANCE
- **DLAD 46.5** ACCEPTANCE
- **DLAD Clause 52.246-9043** HIGHER LEVEL CONTRACT QUALITY REQUIREMENT (NON-MANUFACTURERS)
- **DCMA Inst 303** CRITICAL SAFETY ITEMS-QA
- **DCMA Inst 309** GOVERNMENT CONTRACT QUALITY ASSURANCE (GCQA) SURVEILLANCE PLANNING
- **DCMA Inst 322** QUALITY SYSTEM AUDIT
- **DCMA Inst 326** RISK ASSESSMENT



REFERENCES

- **FAR 42.302**- Ensure supplier complies with contractual QA requirements
- **FAR 46.202-4** - Requires compliance with higher-level quality standards in contracts for complex or critical items
- **FAR 46.4** GOVERNMENT CONTRACT QUALITY ASSURANCE
- **FAR 46.402** - Requires Government QA performance at the source if QA activities elsewhere are uneconomical, unreasonable, or destructive
- **FAR 46.5** ACCEPTANCE
- **FAR 52.246-11** HIGHER LEVEL CONTRACT QUALITY REQUIREMENT



REFERENCES

- http://www.iso.org/iso/home/standards/management-standards/iso_9000.htm
- **ISO 9001-2008** QUALITY MANAGEMENT SYSTEMS REQUIREMENTS – fourth edition
- **ISO 9001-2015** QUALITY MANAGEMENT SYSTEMS REQUIREMENTS – fifth edition
- **ISO 9002** QUALITY SYSTEMS – MODEL FOR QUALITY ASSURANCE IN PRODUCTION, INSTALLATION AND SERVICING
- **MIL-I-45208** INSPECTION SYSTEM REQUIREMENTS
- **MIL-Q-9858** QUALITY PROGRAM REQUIREMENTS
- **SAE AS9100** QUALITY MANAGEMENT SYSTEMS – REQUIREMENTS FOR AVIATION, SPACE AND DEFENSE ORGANIZATIONS
- **SAE AS9003** INSPECTION AND TEST QUALITY SYSTEMS REQUIREMENTS FOR AVIATION, SPACE AND DEFENSE ORGANIZATIONS

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AMERICA'S COMBAT LOGISTICS SUPPORT AGENCY



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